1. **According to a records request of EPA documents, there have been at least 75,000 incident reports involving pets, including 1,698 deaths. Is this a high number? Why is it still sold? Is there any sort of threshold for removing the collar from the market?**

2. **California toxicologists said the Bayer studies the EPA relied on to approve the collars underestimated the harm to adult dogs and cats. However, the EPA approved them. What science is there to support these registrations? How can customers know that these are safe to use?**

Combined Response to the above questions:

EPA takes every incident reported seriously. If any pesticide is found to present unreasonable adverse effects on the environment as defined in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), or is found not to be safe under the Federal Food, Drug and Cosmetic Act, the Agency would take appropriate regulatory action. Any such action would need to be supported by the best-available, peer-reviewed science.

The active ingredients in the Seresto collar are flumethrin and imidacloprid. Ex. 5 Deliberative Process (DP)

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On the Registration process: Under FIFRA, EPA must make a determination that the product will not cause "unreasonable adverse effects on the environment," defined in FIFRA 2(bb) as (in part) "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, the benefits of a product must be weighed against the risks.

To reach a registration decision and inform the label language, the data that EPA requires includes data on pesticide residues, toxicology, companion animal safety, and efficacy. EPA then independently reviews those data to inform the registration decision. EPA uses this information to determine if and how a product may be used. Evaluations for pet products like shampoos, collars and spot-ons rely upon data on companion animal safety, efficacy and safety for humans who may be exposed as a result of product use.

No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk. The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.

3. **It is my understanding that these incidents do not include the main incident reporting system, which likely has additional incidents. Do you have more information about the number of incidents?**

Manufacturers are required under law to report adverse incident information to EPA. Individuals may report incidents potentially associated with use of an EPA-registered product by contacting the product manufacturer, their state lead pesticide agency, the National Pesticide Information Center, or by contacting EPA directly through its Incident Data System.

4. **There have been at least 907 human-related incidents since 2013, according to EPA data. Is this a high number? Is there any sort of threshold for removing the collar from the market?**

As stated in the Flumethrin: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision, dated Sept. 17, 2019, there was a total of 626 incidents in EPA's Main and Aggregate IDSs. Ex. 5 Deliberative Process (DP) were classified as moderate or lower in severity.

EPA also conducted a larger epidemiological analysis of human incident data associated with pyrethroids ([ HYPERLINK "https://www.epa.gov/sites/production/files/2019-08/documents/tier-ii-epidemiology-report.pdf" ], dated April 30, 2019) and found little substantive evidence to suggest a clear, associative or causal relationship between exposure to pyrethroids and adverse effects. EPA will continue to evaluate incident data in future cycles of registration review. EPA may initiate action at any time to address concerns if unreasonable adverse effects are identified. Such actions can range from mandatory label changes to cancellation of the registration.

5. **It is my understanding that Bayer knew about these incidents for years, prior to selling dog collars to Elanco. Did Bayer make Elanco aware of these issues when selling the product to Elanco?**

EPA does not have information on communications between Bayer and Elanco.

6. **From my understanding talking with former EPA staff, Health Canada denied to approve Seresto because of the incident data. Do you have any response to this?**

# Ex. 5 Deliberative Process (DP)